K072010

AUG - 7 2007

Section 5 – 510(k) Summary

General Information

Owner's Name:	Quantum Medical Imaging, LLC
Address:	2002-B Orville Drive North Ronkonkoma, NY 11779-7661
Telephone Number:	(631) 567-5800
Fax Number:	(631) 567-5074
Contact Person:	Mark Camirand; Director Q.A./Compliance
Subject Device Name:	Quantum DiRex System
Common/Usual Name:	Stationary Electrostatic X-Ray System
Product Codes:	LLZ; KPR; MQB
Regulation:	21 CFR 892.2050 / 21 CFR 892.1680 / 21 CFR 892.1650
Classification:	Class II
Predicate Device Names:	Quantum Q-Rad Radiographic System / Agfa DX-S CR System / Agfa DX-Si System / Agfa CR85-X Digitizer / Agfa CR30-X
Manufacturers:	Quantum Medical Imaging, LLC / Agfa Corp.
Premarket Notifications:	K011486 / K053634 / K063421 / K062742 / K062223

Device Description
The Quantum DiRex System is an integrated digital imaging system that combines the currently marketed Quantum Q-Rad Radiographic System with the currently marketed Agfa DX-S CR System (digitizer with NX workstation). The Quantum DiRex System is a combination of these previously cleared systems that have been combined and will be marketed as a single system.

Intended Use
The Quantum DiRex System provides diagnostic quality images to aid the physician with diagnosis. The DiRex can be used to perform radiographic exposures of the skeleton (including skull, spinal column and extremities), chest, abdomen and other body parts.

Performance Testing
Performance data demonstrated that the Quantum DiRex System is substantially equivalent to the predicate devices and/or met pre-determined acceptance criteria. The risks associated with use of the new device were found acceptable when evaluated by standardized risk/hazard analysis techniques. Performance testing was successfully completed on the proposed system in accordance with predetermined protocols based on the system design inputs.

No biocompatibility testing was conducted in support of this 510(k); all patient-contacting materials used in the manufacture of the DiRex System have been previously cleared for similar devices.

Technological Characteristics
The technological characteristics are the same in the proposed and predicate devices.

Conclusion
The Quantum DiRex System meets all the pre-determined acceptance criteria of the testing performed to confirm safety and effectiveness; the DiRex System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Quantum Medical Imaging, LLC
% Mr. Jeff Rongero
Senior Project Engineer, Medical Business Unit
Underwriters Laboratories, Inc.
12 Laboratory Drive
RESEARCH TRIANGLE PARK NC 27709

AUG 21 2013

Re: K072010
Trade/Device Name: Quantum DiRex System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR and MQB
Dated: July 17, 2007
Received: July 23, 2007

Dear Mr. Rongero:

This letter corrects our substantially equivalent letter of August 7, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section 4 – Indications for Use Statement

510(k) Number (if known): K072010

Device Name: Quantum DiRex System

Indications for Use:

The Quantum DiRex System provides diagnostic quality images to aid the physician with diagnosis. The DiRex can be used to perform radiographic exposures of the skeleton (including skull, spinal column and extremities), chest, abdomen and other body parts. The DiRex is not indicated for use in mammography.

Prescription Use __X__ (Per 21 CFR 801 Subpart D) OR Over-the -Counter Use ____ (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072010